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P&G Case 8241

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of :

KAREN A. KREUTZ, et al. :

Confirmation No. 5529

Serial No. 09/653,012 :

Group Art Unit 3761

Filed September 1, 2000 :

Examiner M. Kidwell

For FEMININE HYGIENE KIT

REPLY BRIEF UNDER 37 CFR § 1.193(a)

Mail Stop Appeal Brief - Patents

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

Dear Sir,

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This is an appeal from the final rejection of pending claims 1-6 and 8-20 which was made in an Office Action (Paper No. 17) dated March 26, 2003. A timely notice of appeal was filed on June 26, 2003 and received by the USPTO on June 30, 2003. Appellant's brief was filed on August 27, 2003, and the Examiner's Answer (Paper No. 20) was mailed on December 16, 2003. This Reply Brief is submitted in triplicate.

REPLY TO EXAMINER'S ANSWER

The majority of the Examiner's Answer repeats essentially the same positions previously advanced in the Final Rejection and the Appellants' Appeal Brief adequately addressed these arguments. However, this Reply Brief is being submitted to address one new argument being advanced by the Examiner which merits further discussion.

Page 8 of the Examiner's Answer puts forth a new line of reasoning purporting to show how the Moder et al. patent provides the motivation to modify the reference to provide the missing feature of Claim 1 (i.e. a tampon having a synergistic absorbency of less than 6 grams). This reasoning is, in essence, that Moder et al. teaches sizes corresponding to the disclosed absorbencies and teaches that these can vary. For example, a regular absorbency tampon is disclosed as being **about** 50 mm in width. Due to manufacturing variations, and to the extent that size of the absorbent and overall absorbent capacity are related, this disclosure supposedly

supports the conclusion that the actual absorbency of the finished tampon can be 6.01g or 5.99 grams even though the intended absorbency may be 6 grams.

This reasoning is flawed for several reasons. Firstly, the Examiner's Answer seems to be applying concepts of anticipation to what is an obviousness analysis. The present rejections are all made under § 103, not under § 102. The Examiner has not maintained that *Moder et al.* expressly discloses a syngyna absorbent capacity of less than 6 grams as claimed. Similarly, the Examiner's Answer does not maintain that portions of *Moder et al.* cited on Page 8 of the lead to inherent disclosure of this claim feature. This, of course, is correct as inherent disclosure in a publication cannot be based on possibilities or probabilities. *In re Robertson*, 169 F.3d 743, 49 USPQ 2d 1949 (Fe. Cir. 1999). In this case, the Examiner does not argue that *Moder et al.* inherently discloses the missing claim feature, but uses the possibility of manufacturing variability to conclude that a finished tampon with an absorbency of less than 6 grams would be within the level of ordinary skill in the art (and therefore obvious). This argument about the level of skill in the art has been addressed several times in the Appellants' Brief. It is not sufficient to show that one of ordinary skill in the art **could** have made the claimed invention. The art itself must provide the **motivation** to do so.

In this case, the Examiner's Answer attempts to make too much out of the cited passage from *Moder et al.* As discussed in the Appeal Brief, the provisions of 21 CFR § 801.430 are of record in the instant appeal. This is evidence which must be considered in making the ultimate determination of obviousness. These regulations make clear that a tampon labeled "regular" must be made such that given manufacturing tolerances, the sampling done provides 90% confidence that 90% of the products in the lot are within the required range (i.e. greater than 6 up to and including 9 grams). Statistically, this standard is often referred to as 90/90 confidence level. This result can only be achieved by making the "target" the middle of the range and controlling variation sufficiently to limit the number and magnitude of outlying results. Therefore, it is contrary to record evidence as a whole to take one sentence from *Moder et al.* where "about" is used in conjunction with a representative size and equate this with a recognition of the **desirability** of providing the claimed tampon having a syngyna absorbent capacity of less than 6 grams in combination with the claimed backup feminine protection product.

The cited section of *Moder et al.* does not even support a reading that the "target" capacity may be 6 grams and may vary from this target to wind up at less than 6 grams. Even if it were true that the target capacity could be 6 grams, manufacturing uncertainty would be just as likely to result in a product with an absorbency slightly greater than 6 grams as one with an

absorbency slightly less than 6 grams. The **ability** of one of skill in the art to produce a tampon of the claimed absorbency is not the relevant inquiry in this case. Therefore, even assuming that the initial "target" absorbency of 6 grams premise is true (which, given 21 CFR § 801.430 the weight of the evidence suggests it is not), Moder et al. simply does not provide the requisite motivation and reasonable expectation of success for making the required modifications to its teachings to arrive at the invention of Claim 1. The remainder of the reasoning supposedly showing such motivation in the Examiner's Answer continues to come from the Appellants' own specification and not from the teachings of the prior art.

#### SUMMARY

None of Claims 1-6 and 8-20 has been properly rejected under 35 U.S.C. § 103 in light of the reasoning and analysis given in the Final Office Action, or the Examiner's Answer. In light of all of the analysis and discussion provided in the Appeal Brief, and in this Reply Brief, Appellants respectfully request the Honorable Board of Patent Appeals and Interferences to reverse the rejections of Claims 1-6 and 8-20 and to remand the application with instructions that these claims be allowed over the cited art.

Respectfully submitted,

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